



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,104	08/22/2006	Bjarne H. Dahl	2815-0266PUS2	5129

2292 7590 02/11/2008  
BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER
----------

LOEWE, SUN JAE Y

ART UNIT	PAPER NUMBER
----------	--------------

1626

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

02/11/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	Application No. 10/590,104	Applicant(s) DAHL ET AL.	
	Examiner Sun Jae Y. Loewe	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 29-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                    |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                               | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8-22-2006</u> . | 6) <input type="checkbox"/> Other: _____                                                |

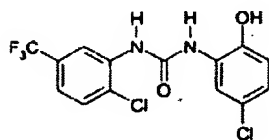
### DETAILED ACTION

1. Claims 1-37 are pending in the instant application. Claim 38 was cancelled by preliminary amendment filed on August 22, 2006.

#### *Election/Restrictions*

2. Applicant's election with traverse of Group I, and species shown below, in the reply filed on December 18, 2007 is acknowledged.

N-(3-chloro-6-hydroxyphenyl)-N'-(2-chloro-5-trifluoromethylphenyl)urea.



The traversal is on the ground(s):

“it would not be unduly burdensome for the PTO to examiner method claims 29-37 along with elected claims 1- 28.” The arguments are not found persuasive for the following reason. The instant application is a national stage entry of PCT/EP05/51183 and thus the criteria of burden (MPEP 800, for national applications filed under 35 USC 111) does not apply. The restriction requirement is still deemed proper and is therefore made FINAL.

3. The following guidelines are provided by MPEP 1893.03(d):

“ Note: the determination regarding unity of inven-

tion is made without regard to whether a group of inventions is claimed in separate claims or as alternatives within a single claim. The basic criteria for unity of invention are the same, regardless of the manner in which applicant chooses to draft a claim or claims.

>If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any non-

¶ 18.20 National Stage Election of Species in 35 U.S.C. 371 Applications

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If "

The elected species was obvious over the prior art (see Section 10). The generic claims encompassing the elected species were not allowable under 35 USC 112 2<sup>nd</sup> Paragraph (Section 8). Furthermore, upon cursory evaluation of the prior art, it appeared that the genus encompassing the elected species is not novel over the art of record (see Section 9).

Pursuant MPEP 1893.03(d), non-elected species were withdrawn from further consideration. In view of the above, the search and examination detailed herein was limited to the elected compound and the non-elected compound discussed in Section 9.

4. Claims 29-37 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter. Applicant timely traversed the restriction (election) requirement in the reply filed on December 18, 2007.

***Priority***

5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

6. The information disclosure statement (IDS) submitted on March 12, 2007 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS was considered. A signed copy of form 1449 is enclosed herewith.

***Claim Objections***

7. Claims 1-28 objected to for containing non-elected subject matter.

***Claim Rejections – 35 USC 112 2<sup>nd</sup> Paragraph***

8. Claims 1-28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to “urea derivative” or pharmaceutical compositions thereof. The term “derivative” is defined as organic compounds obtained from another compound by a simple chemical process or an organic compound containing a structural radical similar to that from which it is derived (Hackh's chemical dictionary, 1972). Therefore, the term “derivative” renders the claims indefinite because the metes and bounds (ie. structural boundary) cannot be ascertained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-23 and 28 rejected under 35 U.S.C. 102(b) as being anticipated by Widdowson et al. (WO 96/25157).

The reference teaches IL-8 receptor antagonists, for example

N-(2-hydroxy 4-nitro phenyl) N'-(2-chloro phenyl) urea , which are encompassed by the instant Markush claims.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

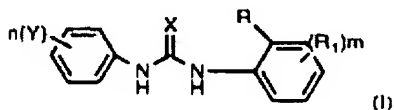
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-28 rejected under 35 U.S.C. 103(a) as being obvious over Widdowson et al. (WO 96/25157).

Determination of the scope and contents of prior art.

The reference teaches the following genus of compounds as IL-8 receptor antagonists:



Formula I is defined to include the following embodiments for variables Y, X, R and R<sub>1</sub> (see pg. 3):

H, Halogen, Haloalkyl	for Y
Oxygen	for X
OH	for R (see p. 110)
Halogen, NO <sub>2</sub> , CN, Alkyl	for R <sub>1</sub>

The disclosure provides multiple species which fall into the subgenus defined by these embodiments:

N-(2-Hydroxy-4-fluorophenyl)-N'-(phenyl) urea  
N-(2-Hydroxy-4-nitrophenyl)-N'-(3-trifluoromethylphenyl) urea  
N-[2-Hydroxy-3-fluoro-5-bromophenyl]-N'-(2-bromophenyl) urea  
N-[2-Hydroxy-3,5-dichlorophenyl]-N'-(2-bromophenyl) urea  
N-[2-Hydroxy-4-cyanophenyl]-N'-(3-trifluoromethylphenyl) urea  
N-(2-Hydroxy-3,5,6-trifluorophenyl)-N'-(2-bromophenyl) urea  
N-[2-Hydroxy-5-fluorophenyl]-N'-(2-bromophenyl) urea  
N-[2-Hydroxy-3,4-dichlorophenyl]-N'-(3-trifluoromethylphenyl) urea  
N-[2-Hydroxy-3,4-dichlorophenyl]-N'-(2,3-dichlorophenyl) urea  
N-[2-Hydroxy-4-isopropylphenyl]-N'-(3-trifluoromethylphenyl) urea  
N-[2-Hydroxy-5-nitrophenyl]-N'-(3-trifluoromethylphenyl) urea  
N-(2-hydroxy-4-nitrophenyl)-N'-(2-chlorophenyl) urea

Ascertaining the differences between prior art and instant claims.

The instantly elected compound, N-(3-chloro-6-hydroxyphenyl)-N'-(2-chloro-5-trifluoromethylphenyl) urea, is not expressly taught by the prior art.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.

The subgenus noted above is drawn to a finite number of species, including the instantly elected compound, that can be obtained by the substitution of the variables into the core structure. Applicant's elected species of N-(3-chloro-6-hydroxyphenyl)-N'-(2-chloro-5-trifluoromethylphenyl) urea, is encompassed by this subgenus. Thus, the reference of Widdowson et al. suggests to

one of ordinary skill to make the elected compound. One of ordinary skill would be motivated to make such compound, with a reasonable expectation of success, in order to produce additional IL-8 antagonists.

Thus, N-(3-chloro-6-hydroxyphenyl)-N'-(2-chloro-5-trifluoromethylphenyl)urea is prima facie obvious over the disclosure of Widdowson et al.

Note: Alternate prior art references are available that can be applied in a similar rejection as set forth in this section (eg. WO 02/064139, WO 94/22807, WO 00/01349). However, in view of the guidelines presented in MPEP 706.02, the "best available" prior art was chosen (ie. disclosure of Widdowson et al.); only this reference was used in a 35 USC 103 rejection.

### *Conclusion*

11. No claims allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sun Jae Y. Loewe whose telephone number is (571) 272-9074.

The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Application/Control Number:  
10/590,104  
Art Unit: 1626

Page 8

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SL  
2-1-2008

REBECCA ANDERSON  
PRIMARY EXAMINER

Rebecca Anderson  
Primary Examiner  
Art Unit 1626